



DEPARTMENT OF HEALTH & HUMAN SERVICES

NFI-35
Public Health Service
Food and Drug Administration

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Dallas District
3310 Live Oak Street
Dallas, Texas 75204-6191

August 8, 2000

Ref: 2000-DAL-WL- 13

WARNING LETTER

VIA FEDERAL EXPRESS

Mr. Durian Alsaifi
President
Commerce Fresh Marketing, Inc.
7120 Brittmoore Rd., Suite 420
Houston, Texas 77041

Dear Mr. Alsaifi:

Our investigator conducted an inspection of your fresh produce manufacturing facility at 7120 Brittmoore Road, Suite 420, Houston, Texas, on July 18-19, 2000. This inspection disclosed practices at your facility that concern us and cause your alfalfa sprouts to be in violation of the Federal Food, Drug and Cosmetic Act (the Act).

Specifically, our inspection revealed that your sprouts are adulterated within the meaning of section 402(a)(4) of the Act because they are being produced under insanitary conditions that may render the sprouts injurious to health. The conditions under which the sprouts are being produced are considered insanitary since effective preventive controls, particularly microbial testing of spent irrigation water, have not been implemented at your facility and an effective alternative is not in place.

This violation is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations.

You should take prompt action to correct this deviation. Failure to promptly correct this deviation may result in FDA taking regulatory action without further notice. These actions include, but are not limited to seizure, and/or a court injunction. During the inspection, our investigator provided you with copies of two guidance documents intended to assist the sprout industry in producing safe products, "Sampling and Microbial Testing of Spent Irrigation Water During Sprout Production" and "Reducing Microbial Food Safety Hazards for Sprouted

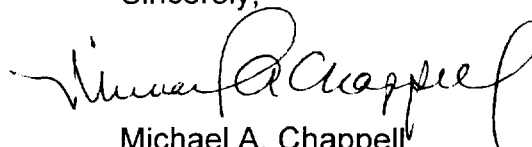
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Seeds." To address our concerns, you could follow the guidance provided in these documents or establish an alternative approach that satisfies the requirements of the Act and regulations.

It is necessary for you to take action on this matter now. Please let this office know in writing within fifteen (15) working days from the date you receive this letter what steps you are taking to correct the problem. We also ask that you explain how you plan to prevent this violation from happening again. If you need more time, let us know why and when you expect to complete your corrections.

Your reply should be sent to Gwendolyn Sue Gilbreath, Compliance Officer, at the above address.

Sincerely,

A handwritten signature in black ink, appearing to read "Michael A. Chappell", written in a cursive style.

Michael A. Chappell
Dallas District Director

MAC:gsg

cc: Mr. Ronnie L. Mahr
Vice President